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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,894	09/11/2003	Sebastian Vogt	100727-57/Heracus 409-KGB	4182
27384	7590	10/02/2008	EXAMINER	
NORRIS, MCLAUGHLIN & MARCUS, PA 875 THIRD AVENUE 18TH FLOOR NEW YORK, NY 10022			ROGERS, JAMES WILLIAM	
			ART UNIT	PAPER NUMBER
			1618	
			MAIL DATE	DELIVERY MODE
			10/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/659,894

Applicant(s)

VOGT ET AL.

Examiner

JAMES W. ROGERS

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4-13 and 15-30 is/are pending in the application.
- 4a) Of the above claim(s) 4, 7, 9, 11-13, 17, 21-25 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4-6, 8, 10, 15-20, 26 and 28-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

The amendments to the claims filed 07/11/2008 has been entered. Any objection/rejection from the previous office action filed 01/11/2008 not addressed in the action below has been withdrawn.

Response to Arguments

Applicant's arguments filed 07/11/2008 have been fully considered but they are not persuasive.

Applicants assert that the examiner should examine the full scope of claim 28 and nothing has changed in claims 4,7,9,11-13 and 17 that caused their continued examination to become a burden.

The relevance of these assertions is unclear. Claim 28 has been fully examined. Claims 4,7,9,11-13 and 17 were all previously unelected from the response to election/restriction filed 06/12/2006 and were withdrawn by the examiner in the action filed 07/10/2006.

Claims 15-16,18,20,26, 28 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Whitbourne et al. (US 6,110,483), for the reasons set forth in the previous office action filed 01/11/2008.

Claims 2,4-6,8,10,15-20,26 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitbourne et al. (US 6,110,483) in view of Watanakunakom et al., ("Effects of combinations of clindamycin with gentamicin, tobramycin, and amikacin

against *Staphylococcus aureus*," in *Journal of Antimicrobial Chemotherapy* (1980), Vol. 6, No. 6, abstract of pp. 785-791) in view of McGhee (US 6,110,483) in view of Rozzi et al. (US 2003/0138492 A1), for the reasons set forth in the previous office action filed 01/11/2008.

Applicants assert that Whitbourne cannot anticipate their claimed combination in the arrangement required by the claims, that is a,b and c which are the organic substances are suspended in element d which is a homogeneous polymer mixture. Applicants further assert that the examiners reliance on inherency is flawed since the examiner has not pointed to where the reference states that the active ingredient must be necessarily dispersed in the polymer/solvent mixture. Applicants further assert that none of the secondary references disclose the above defects of Whitborne thus the combination fails to make a prima facie case of obviousness.

The relevance of these assertions is unclear. Firstly it is noted by the examiner that applicants arguments only pertain to claim 28 and the claims that dependent upon it, however claim 2 and 26 do not require that a,b and c are suspended within d. Secondly applicants limitation that a and optionally b and c are suspended in the polymer mixture d, is not seen as very limiting, any pharmaceutical composition that contains a drug and a polymer that is admixed will clearly have some drug suspended within the polymer. The examiner interpreted suspended in its broadest reasonable interpretation to mean particles that are supported or kept from falling by another material. Clearly Whitbourne states that the active is entrapped within the polymer

mixture, it is inherent that since the active is entrapped within the mixture it is also necessarily suspended within the polymer mixture.

Conclusion

No claims are allowed at this time.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published

applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618